# PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

# PCT

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
*(day/month/year)* see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

**FOR FURTHER ACTION**
See paragraph 2 below

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/US2004/025789 | 10.08.2004 | 14.08.2003 |

International Patent Classification (IPC) or both national classification and IPC
C07K16/42, C07K16/28

Applicant
WYETH

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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EV321878429US

**WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/025789

**Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/025789

**Box No. II Priority**

1. ☐ The following document has not been furnished:

   ☐ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

   Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. ☒ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

4. Additional observations, if necessary:

**Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | none |
| | No: | Claims | 1-23 |
| Inventive step (IS) | Yes: | Claims | none |
| | No: | Claims | 1-23 |
| Industrial applicability (IA) | Yes: | Claims | 1-23 |
| | No: | Claims | none |

2. Citations and explanations

**see separate sheet**

**Re Item V.**

1. The following documents are referred to in this communication:
   D1 : LIU Z. ET AL, HYBRIDOMA AND HYBRIDOMICS 22:219-228. AUG 2003
   D2 : HIRASHIMA K ET AL, J. IMMUNOLOGY 145:224-232, 1990
   D3 : ROSOK M J ET AL, J. IMMUNOLOGY 160:2353-2359, 1998
   D4 : SCOTT A M ET AL, CANCER RESEARCH 60:3254-3261, 2000
   D5 : CLARKE K ET AL, CLINICAL CANCER RESEARCH 6:3621-3628, 2000
   D6 : WO 93/24647 A
   D7: BHATTACHARYA-CHATTERJEE M ET AL, CURRENT OPINION IN MOLECULAR THERAPEUTICS 3:63-69, 2001

2.1 D1 which appears to have been publicly available befor the priority date discloses the anti-idiotypic (anti-Id) antibodies LMH-1, -2, and -3 against hu3S193 monoclonal antibody (mAb), hybridomas producing said anti-Id, and uses thereof. As the technical features of all claims are present in D1, the **entire claim set** lacks novelty in the sense of **Article 33(2) PCT** in view of D1.

2.2 D2 discloses mAb AH-6 agains Lewis Y (LeY) antigen, and two anti-Id, namely Id-A1 and Id-B4 directed against AH-6. D2 further relates to ELISA using immobilised AH-6 to detect anti-Id antibodies. Consequently, **claims 1-3, 5-7, 9, 10, 15, and 17** lack novelty in the sense of **Article 33(2) PCT** in view of D2. The **remaining claims** lack an inventive step in the sense of **Article 33(3) PCT** because they relate to subject-matter which is obvious in view of D2 when combined with the common general knowledge in the field at the time of filing (see e.g., D4-D7).

2.3 D3 discloses mAb BR96 directed agains LeY, and anti-Id 757 directed against BR96. D3 further relates to ELISA with immobilised synthetic LeY conjugated to human serum albumin (HSA). Consequently, **claims 1-3, 5-7, and 9-11** lack novelty in the sense of **Article 33(2) PCT** in view of D3. The **remaining claims** lack an inventive step in the sense of **Article 33(3) PCT** because they are obvious in view of D3 in combination with common scientific knowledge.

3. The terms "hu3S193" in **claims 4, 16, 19 and 22,** and "LMH-1", "LMH-2", and "LMH-

3" in **claims 13 and 14,** are arbitrary designations without meaning to the skilled reader. The claims are therefore unclear in the sense of **Article 6 PCT.** Likewise, the term "HAHA response" in **claim 23** is unclear.

4. **Claim 23** in its present form is directed to a method of treatment or diagnosis practiced on the human or animal body. No unified criteria exist in the PCT contracting states for the patenting of such methods, however, under Article 17(2)(a)(i) and Rule 39.1(iv) PCT, the EPO is not required to search or examine said claims. In the EPO, methods of treatment or diagnosis practiced on the human or animal body are considered non-patentable, whereas compounds or compositions for use in such methods can be patented.